

Determination of the radiochemical purity of ^{99m}Tc -tetrofosmin: Comparison between five methods

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GOAL: The manufacturing and distribution of strips of instant thin-layer chromatography with silica gel (ITLC-SG) (reference method) is currently discontinued so there is a need for an alternative method for the determination of radiochemical purity (RCP) of ^{99m}Tc -tetrofosmin. This study aims to compare five alternative methods proposed by the producer to determine the RCP of ^{99m}Tc -tetrofosmin.

METHODS: Nineteen vials of tetrofosmin were radiolabelled with ^{99m}Tc and the percentages of the RCP were determined. Five different methods were compared with the standard RCP testing method (ITLC-SG, 2x20 cm): Whatman 3MM (1x10 cm) with acetone and dichloro-methane (method 1); Whatman 3MM (1x10 cm) with ethyl acetate (method 2); aluminum oxide-coated plastic thin-layer chromatography (TLC) plate (1x10 cm) and ethanol (method 3); Whatman 3MM (2x20 cm) with acetone and dichloro-methane (method 4); solid-phase extraction method C18 cartridge (method 5).

RESULTS: The average values of RCP were $95,30\% \pm 1,28\%$ (method 1), $93,95 \pm 0,61\%$ (method 2), $96,85\% \pm 0,93\%$ (method 3), $92,94\% \pm 0,99\%$ (method 4) and $96,25\% \pm 2,57\%$ (method 5) (n=12 each), and $93,15\% \pm 1,13\%$ for the standard method (n=19). There were statistical significant differences in the values obtained for methods 1 (P=0,001), 3 (P=0,000) and 5 (P=0,004), and there were no statistical significant differences in the values obtained for methods 2 (P=0,113) and 4 (P=0,327).

CONCLUSION: From the results obtained, methods 2 and 4 showed a higher correlation with the standard method. Unlike method 4, method 2 is less time-consuming than the reference method and can overcome the problems associated with the solvent toxicity. The remaining methods (1, 3 and 5) tended to overestimate RCP value compared to the standard method.

Keywords: ^{99m}Tc -tetrofosmin, quality control, thin-layer chromatography.

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